

### REMARKS

Claims 1 - 3, 9, 11 - 14, 33 - 35, 38 and 41 have been canceled. Claims 8, 36, 37, 39 and 40 have been amended. New claims 42 - 45 have been added. No new matter has been added. Thus, claims 4 - 8, 10, 15 - 32, 36, 37, 39, 40 and 42 - 45 are now pending in the present application. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 36 and 37 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,261,601 to Ross et al. ("Ross"). 6/5/08 Office Action, p. 3.

Amended claim 36 recites a method for needleless injection of a liquid substance into a target biological tissue, the method comprising "generating droplets of the liquid substance" and *"accelerating the droplets of the liquid substance at a velocity sufficiently high to inject the droplets of the liquid substance into the target biological tissue"* in combination with *"directing the droplets of the liquid substance toward a surface of the target biological tissue at the sufficiently high velocity to inject the droplets of the liquid substance into the target biological tissue"* wherein *"generating the droplets of the liquid substance comprises injecting a pressurized gas from a pressurized source into a reservoir containing the liquid substance to force the liquid substance from the liquid reservoir through at least one micro-orifice of a perforated membrane to thereby produce a jet of the liquid substance, wherein the jet of the liquid substance transforms into a stream of the droplets."*

In contrast, Ross discloses a dispensing apparatus in which droplets are generated and ejected under pressure generated by vibration of a transducer. Specifically, Ross describes a hand held dispensing apparatus 1 for oral inhalation. Ross, col. 3, ll. 31-32. The apparatus 1 comprises a housing 2 defining a chamber 3 containing liquid to be dispensed. *Id.* at col. 3, ll. 32-34. An electro-acoustic transducer 8 is mounted on the housing 2. *Id.* at col. 3, ll. 37-39. The housing 2 includes a disc 11 having an aperture 12 with a thin perforated membrane 13

bonded to the disk 11 over the aperture 12 such that a vibration of the transducer 8, upon actuation, causes a fine mist of atomised liquid to be dispensed through the membrane 13 to be inhaled by a user. *See Id.* at col. 3, ll. 45-48 and col. 4, ll. 28-46. Therefore, Ross specifically teaches that the mist of liquid is generated by a pressure created by the *vibration* of the transducer and does not show or suggest any pressurized gas being inserted into the chamber 3 to form droplets of liquid. Thus, Ross does not show or suggest generating droplets of liquid by *“injecting a pressurized gas from a pressurized source into a reservoir containing the liquid substance to force the liquid substance from the liquid reservoir through at least one micro-orifice of a perforated membrane,”* as recited in claim 36.

Moreover, it is respectfully submitted that since the droplets of liquid generated by Ross are inhaled by the user, the velocity of the droplets of liquid cannot possibly be high enough such that the droplets can be directed toward a surface of biological tissue to be injected therein. Though the droplets may be ultimately delivered to the lungs of a patient, the liquid is delivered to the lungs via inhalation by the patient. A “fine mist of atomised liquid” as described by Ross, cannot possibly achieve a velocity sufficiently high to penetrate a surface of the lungs or other biological tissue. Indeed, inhalation of the atomised liquid would not be possible if the droplets of liquid were to penetrate the mouth’s biological tissues. Thus, it is respectfully submitted that Ross does not show or suggest *“accelerating the droplets of the liquid substance at a velocity sufficiently high to inject the droplets of the liquid substance into the target biological tissue”* in combination with *“directing the droplets of the liquid substance toward a surface of the target biological tissue at the sufficiently high velocity to inject the droplets of the liquid substance into the target biological tissue,”* as recited in claim 36.

Accordingly it is respectfully submitted that claim 36 is not anticipated by Ross and that the rejection of this claim should be withdrawn.

Similarly, claim 37 recites a needleless syringe for injecting a liquid substance into a target biological tissue, comprising “a generator of droplets of the liquid substance” and “a

*droplet accelerator for accelerating the droplets of the liquid substance toward a surface of the target biological tissue in order to inject the accelerated droplets into the target biological tissue*” wherein the generator of droplets comprises “a reservoir of the liquid substance to be injected” and “a perforated membrane comprising at least one micro-orifice through which the liquid substance from the reservoir is supplied” in combination with “a source of pressurized gas” and “a valve for connecting the source of pressurized gas to the reservoir of the liquid substance, wherein opening of the valve causes pressurized gas from the source to be supplied to the reservoir for pressurizing the reservoir of the liquid substance and forcing the liquid substance through the at least one micro-orifice of the perforated membrane to thereby produce a jet of the liquid substance, wherein the jet of the liquid substance transforms into a stream of the droplets.”

For at least the same reasons as discussed above in regard to claim 36, it is respectfully submitted that claim 37 is not anticipated by Ross and that the rejection of this claim should be withdrawn.

Claims 39 - 41, 4 - 10, 15 - 32 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ross in view of U.S. Patent No. 5,630,796 to Bellhouse et al. (“Bellhouse”). 6/5/08 Office Action, p. 3. The Examiner states that Ross discloses the invention substantially as claimed except for high velocity jet of gas and supplying and conveying the droplets into the jet of gas and guiding the jet of gas through a channel toward a surface of the biological tissue. The Examiner cites Bellhouse to cure this deficiency.

Amended claim 39 recites a method for needleless injection of a liquid substance into a target biological tissue, comprising “generating a high velocity jet of gas” and “generating droplets of the liquid substance” in combination with “supplying and conveying the droplets of the liquid substance into the high velocity jet of gas” and “guiding the high velocity jet of gas through a channel toward a surface of the target biological tissue for injecting the conveyed droplets of the liquid substance into the target biological tissue” wherein generating the droplets

of the liquid substance comprises “containing the liquid substance into a reservoir” and “interposing a perforated membrane between the reservoir and the channel in such a manner that *the flow of the high velocity jet of gas is guided along a face of the perforated membrane on a side of the perforated membrane opposite to the reservoir of the liquid substance*” in combination with “pressurizing the reservoir containing the liquid substance to force the liquid substance from the liquid reservoir through the perforated membrane to thereby produce a jet of the liquid substance that transforms into *a stream of the droplets supplied within the high velocity jet of gas laterally of the direction of the flow said high velocity jet of gas.*”

It is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to modify Ross with the source of pressurized gas of Bellhouse. As discussed above in regard to claim 36, Ross does not describe a device and method for a needless injection of a liquid substance. Rather, Ross describes a generation of droplets for inhalation such that the velocity of droplets generated by the transducer are not sufficiently high for the droplets to penetrate a surface of biological tissue. Thus, it is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to combine the dispensing apparatus of Ross with the needleless transdermal power injector as taught by Bellhouse.

Even if, however, the invention of Ross were combined with the pressurized gas source of Bellhouse, it is respectfully submitted that Bellhouse would not cure the deficiency of Ross. As acknowledged by the Examiner, Ross does not disclose a high velocity jet of gas. However, it is respectfully submitted that Bellhouse describes neither a high velocity jet of gas guided along a perforated membrane on a side opposite a reservoir nor a stream of droplets supplied within the high velocity jet of gas laterally of the direction of the flow of the high velocity of gas. Specifically, Bellhouse describes syringe with a reservoir 11 of a barrel portion 10 charged with gas such that by screwing a supply conduit onto a skirt 15, and depressing a plunger 16, the reservoir 11 is charged by flow upwards into a chamber 25 toward a capsule 28 to burst diaphragms 33, 34. *Bellhouse*, col. 13, ll. 6-9 and 24-28; *see* Fig. 1. Gas then travels through the nozzle 26 into the patient's skin. Thus, it is respectfully submitted that the pressurized gas flows

through the syringe such that it is neither guided along a face of a membrane opposite the reservoir nor does it flow laterally of the particles injected into the patient's skin. Thus, it is respectfully submitted that Bellhouse does not teach high velocity gas that is guided along a face of a membrane opposite of the reservoir or a stream of droplets lateral to the flow of the gas.

Accordingly, it is respectfully submitted that neither Ross nor Bellhouse, either alone or in combination, show or suggest "interposing a perforated membrane between the reservoir and the channel in such a manner that *the flow of the high velocity jet of gas is guided along a face of the perforated membrane on a side of the perforated membrane opposite to the reservoir of the liquid substance*" in combination with "pressurizing the reservoir containing the liquid substance to force the liquid substance from the liquid reservoir through the perforated membrane to thereby produce a jet of the liquid substance that transforms into *a stream of the droplets supplied within the high velocity jet of gas laterally of the direction of the flow said high velocity jet of gas,*" as recited in claim 39.

Thus, it is respectfully submitted that claim 39 is not rendered obvious by Ross in view of Bellhouse. Because claims 4 - 8 and 10 depend from and include all of the limitations of claim 39, it is respectfully submitted that these claims are also allowable.

Similarly, claim 40 recites, in relevant portion, a needleless syringe for injecting a liquid substance into a target biological tissue, comprising "a generator of high velocity jet of gas" and "a generator of droplets of the liquid substance having an outlet for supplying the droplets of the liquid substance into the high velocity jet of gas whereby the droplets of the liquid substance are conveyed within the high velocity jet of gas" in combination with "a channel for guiding the high velocity jet of gas toward a surface of the target biological tissue to thereby inject the conveyed droplets of the liquid substance into the target biological tissue" wherein the generator of the droplets of the liquid substance comprises "a reservoir containing the liquid substance" and "a perforated membrane interposed between the reservoir of the liquid substance and the channel for guiding the high velocity jet of gas" in combination with "a source of pressurization of the

reservoir containing the liquid substance to force the liquid substance from the liquid reservoir through the perforated membrane to thereby produce a jet of the liquid substance that transforms into a stream of the droplets” and *“wherein the perforated membrane is interposed between the liquid reservoir and the channel for guiding the flow of the high velocity jet of gas along a face of the perforated membrane on a side of the perforated membrane opposite to the liquid reservoir, whereby the jet of the liquid substance and the generated droplets of the liquid substance are supplied within the high velocity jet of gas laterally of the direction of the flow of said high velocity jet of gas.”*

For the same reasons as discussed above in regard to claim 39, it is respectfully submitted that claim 40 is not rendered obvious by Ross in view of Bellhouse and that the rejection of this claim should be withdrawn. Because claims 15 - 32 depend from and include all of the limitations of claim 40, it is respectfully submitted that these claims are also allowable.

New claim 42 recites, in relevant portion, generating droplets of the liquid substance comprising “applying, by means of the pressurized gas in the gas-tight chamber, a pressure to a slidable piston interposed between the gas-tight chamber and a reservoir of the liquid substance to be injected” and “compressing the liquid substance in the liquid reservoir by means of the pressure applied to the slidable piston to force the liquid substance through at least one micro-orifice of a perforated membrane to thereby produce a jet of the liquid substance, wherein the jet of the liquid substance transforms into a stream of the droplets.”

Similarly, claim 43 recites, in relevant portion, a generator of droplets comprising “a slidable piston interposed between the liquid reservoir and the gas-tight chamber” wherein “opening of the valve to supply pressurized gas from the source to the gas-tight chamber applies a pressure on the slidable piston to compress the liquid substance in the liquid reservoir and force the liquid substance through the at least one micro-orifice of the perforated membrane to thereby produce a jet of the liquid substance, wherein the jet of the liquid substance transforms into a stream of the droplets.”

Claim 44 recites, in relevant portion “generating the droplets of the liquid substance comprises containing the liquid substance in a cylindrical reservoir positioned coaxial within the channel, the cylindrical reservoir comprising a downstream perforated membrane and an upstream slidable piston and the liquid substance being contained in the cylindrical reservoir between the perforated membrane and the slidable piston” and “generating the high velocity jet of gas comprises releasing upstream of the channel pressurized gas to produce the high velocity jet of gas” wherein “pressurized gas released in the channel applies a pressure to the slidable piston to compress the liquid substance in the liquid reservoir and force the liquid substance through the perforated membrane to thereby produce a jet of the liquid substance, the jet of the liquid substance transforming into a stream of the droplets supplied in the high velocity jet of gas.”

Similarly, claim 45 recites a generator of droplets of liquid, “wherein the generator of the droplets of the liquid substance comprises a cylindrical reservoir containing the liquid substance and positioned coaxial within the channel, the cylindrical reservoir comprising a downstream perforated membrane and an upstream slidable piston and the liquid substance being contained in the cylindrical reservoir between the perforated membrane and the slidable piston” and “wherein the generator of the high velocity jet of gas comprises a source of pressurized gas positioned upstream of the channel to release in the channel pressurized gas to produce the high velocity jet of gas” and “wherein pressurized gas released from the source applies a pressure to the slidable piston to compress the liquid substance in the liquid reservoir and force the liquid substance through the perforated membrane to thereby produce a jet of the liquid substance, the jet of the liquid substance transforming into a stream of the droplets supplied in the high velocity jet of gas.”

It is respectfully submitted that neither Ross nor Bellhouse, either alone or in combination, show or suggest a slidable piston and/or a cylindrical liquid reservoir coaxial to in the channel as recited in claims 42 - 45. Thus, it is respectfully submitted that these claims are also allowable.

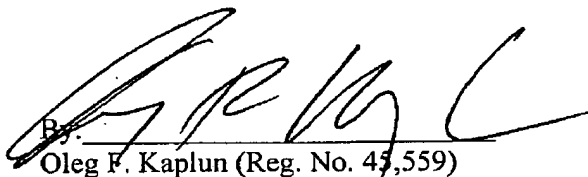
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CONCLUSION

In light of the foregoing, Applicants respectfully submit that all of the presently pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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